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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/675,818 | 09/29/2003 | Mark B. Knudson | 14283.1USI2 | 6678 |

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| EXAMINER | |
|---|---|
| REIDEL, JESSICA L | |
| ART UNIT | PAPER NUMBER |
| 3766 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/13/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/675,818 | KNUDSON ET AL. | |
| | Examiner | Art Unit | |
| | Jessica L. Reidel | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 6-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on October 27, 2006. Claims 2-5 and 9-14 have been cancelled. Claims 1 and 6-8 are pending.

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on October 27, 2006 has been acknowledged and is being considered by the Examiner.

3. Applicant should note that the large number of references in the attached IDS (both previously submitted and newly submitted) have been considered by the Examiner in the same manner as other documents in Office search files are considered by the Examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this Office Action.

### *Specification*

4. The Abstract of the disclosure is objected to because it does not allow for one to determine quickly, from cursory inspection, the nature and gist of the technical disclosure and correspondingly claimed subject matter. Since the scope of the claims has been significantly changed by the Amendment submitted on October 27, 2006, the Examiner respectfully requests that Applicants modify the Abstract to more accurately reflect the claimed invention. As noted by the court in recent decisions, the Abstract may be used to determine the meaning of claims.

See *Pandrol USA, LP v. Airboss Railway Products, Inc.*, 320 F.3d 1354, 1363 n.1, 65 USPQ2d 1985, 1996 n.1 (Fed. Cir. 2003), *Hill-Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 n.1, 54 USPQ2d 1437,1443 n.1 (Fed. Cir. 2000). Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: the newly submitted CROSS-REFERENCE TO RELATED APPLICATIONS needs to be updated with the current status of all listed applications. U.S. patent application Ser. No. 10/358,093 has been abandoned, for example. The Examiner respectfully requests that the information in be updated along with any other U.S. patent applications that have since been issued or abandoned. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 8 both recite the limitation "said proximal nerve conduction block" in the first and second lines of each claim. There is insufficient antecedent basis for these limitations in the claims.

### *Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by King (U.S. 6,928,320). King expressly discloses a method for treating movement disorders of the gastrointestinal tract of a patient (i.e. assisting peristalsis) by applying a high frequency/DC neural conduction block (via electrodes 32 and 39) to a vagal branch or trunk 46 innervating an alimentary track organ (i.e. esophagus 38 and/or stomach 35). King also discloses that the high frequency/DC neural conduction block prevents the low frequency intended stimulation (via electrodes 31, 33 and 34) from causing undesirable effects (see King Fig. 7 and column 8, lines 27-55). Since low frequency stimulation electrodes 31, 33 and 34 are located on both sides of neural conduction blocking electrode 32, it is inherent that the high frequency/DC neural conduction block applied via electrode 32 "at least partially blocks" nerve impulses traveling in both afferent and efferent directions since this is an established objective of King. Furthermore, King expressly discloses that the high frequency blocking employed by the method, as discussed above, is an improvement over prior art "partial-blocking" techniques (see King column 2, lines 38-67). In addition, King specifies that the high frequency blocking is accomplished via electrical conduction block of about 100-120 Hz or via a straight direct current pulse (see King columns 5-6). It is inherent that such high frequency blocking or DC blocking "at least partially blocks" nerve impulses traveling in both afferent and efferent directions and the Examiner makes reference to Applicants' disclosure pages 22-23. King expressly discloses that DC blocking prevents neural tissue from developing action potentials and action potentials that approach the

region of the block run into areas where neuronal sodium gates are already affected and thus cannot open (see King column 6, lines 29-37).

*Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler et al. (U.S. 5,747,060) (herein Sackler). Sackler expressly discloses a method for treating acute pancreatitis, ileus or other visceral disorders comprising applying a pharmacologic neural conduction block with the block selected to at least partially block both afferent and efferent nerve impulses at a site of application of the block. Sackler also specifies that the pharmacologic neural conduction block may be applied for blockade of both sympathetic or parasympathetic ganglia and cranial nerves and that applications include "any condition for which localized nerve

blockade is desirable" such as for relief of pain and motor symptoms as well as nerve blockade for other medical purposes (see Sackler Abstract, column 1, lines 4-9, column 5, lines 25-61 and column 15, lines 35-60). Sackler discloses the claimed invention as discussed above except that it is not specified that the pharmacologic neural conduction block be applied to a vagal branch or trunk. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Sackler, to include application of the pharmacologic neural conduction block to a vagal branch or trunk since it was known that the vagus nerve is a nociceptive pathway of the enteric nervous system which anatomically innervates alimentary tract organs affected by acute pancreatitis, ileus and other visceral disorders.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler in view of Dobak, III (U.S. 6,364,899) and Carroll (U.S. 2002/0161360. Applicant differs from the previously modified Sackler reference in that the nerve conduction block is a cryogenic block (versus the pharmacologic block of Sackler). The Examiner considers the use of cryoanalgesia to be conventional and well-known techniques of nerve blocking, an obvious variant of a pharmacologic block, and provides Doback, III and Carroll as examples.

***Double Patenting***

14. In view of the response submitted on October 27, 2006 all of the non-statutory double patenting rejections made in the Office Action of April 26, 2006, have been withdrawn.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1 and 6-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-30 of copending Application No. 10/881,045. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the current claims are either an obvious broadening of the scope of the conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1 and 6-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 7,167,750. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

***Terminal Disclaimer***

18. The terminal disclaimer filed on October 27, 2006 disclaiming the terminal portion of any patent granted on this application has been reviewed and is NOT accepted. As previously stated, in view of the response submitted on October 27, 2006 *all* of the non-statutory double patenting rejections made in the Office Action of April 26, 2006, have been withdrawn [emphasis added]. Regarding Applications 10/674,324 and 10/756,176, the rejections made in the Office Action of April 26, 2006 have been withdrawn in view of Amendments made to the current application and amendments made in the conflicting applications. Regarding Application 11/192,750, the rejections made in the Office Action of April 26, 2006 have been withdrawn since the assignee of the current application differs from that of the conflicting application.

### *Response to Arguments*

19. Applicant's arguments with respect to claims 1 and 6-8 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Saadat (U.S. 6,746,474) teaches the use of cryogenic blocks to diminish nerve impulses on a plurality of nerves including the vagus nerve.

Yun et al. (U.S. 2004/0249416) (herein Yun '416) teaches methods for up-regulating parasympathetic activity (e.g. via the vagus nerve) and down regulating -- using high frequency blocking signals -- sympathetic activity (e.g. via the sympathetic spinal nerves) to treat a wide variety of disorders, including obesity.

Yun et al. (U.S. 2005/0143378) (herein Yun '378) teaches methods for up-regulating parasympathetic activity (e.g. via the vagus nerve) and down regulating sympathetic activity using pharmacological or electrical means. Yun '378 teaches that it is possible to down-regulate the parasympathetic nervous system (see Yun '378 pages 18-19) via a method comprising positioning an electrode at or near a parasympathetic nerve and applying an electrical signal to the electrode with the signal selected to, at least in part, down-regulate neural activity on the nerve but does not, however, disclose or suggest that down-regulating the parasympathetic system can be used to treat obesity. Yun '378 is generally related to increasing parasympathetic activity relative to sympathetic activity for treating obesity.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel 02/07/07
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766